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[10121/00901]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Sullivan
Serial No. : 09/603,886
Filed : June 26, 2000
For : Vascular Access Port
Group Art Unit : 3737
Examiner : Ruth S. Smith

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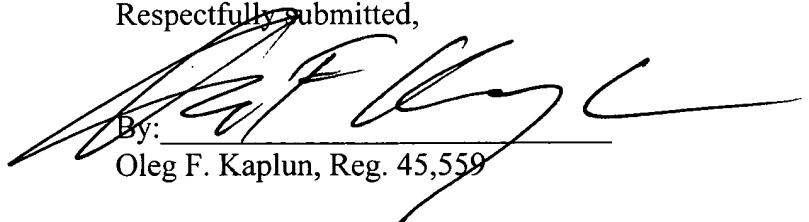
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By: 	Date: October 7, 2005
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TRANSMITTAL

In response to the Notice of Appeal filed August 9, 2005 and the Advisory Action dated June 9, 2005, transmitted herewith please find an Appeal Brief (in triplicate) for filing in the above-identified application. Please charge the Credit Card of **Fay Kaplun & Marcin, LLP** in the amount of \$500.00 (PTO-Form 2038 is enclosed herewith). The Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492** for any additional required fees. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: October 7, 2005


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PATENT
Attorney Docket No.: 10121/00901

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re: Application of:)	
)	
Roy Sullivan)	
)	
Serial No.: 09/603,886)	Group Art Unit: 3737
)	
Filed: June 26, 2000)	Examiner: Ruth S. Smith
)	
For: APPARATUS AND METHOD)	
FOR PERFORMING A TISSUE)	Board of Patent Appeals and
RESECTION PROCEDURE)	Interferences

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed August 9, 2005, and pursuant to 37 C.F.R. § 41.37, Appellant presents in triplicate an appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 33 - 42 in the final Office Action dated March 31, 2005 and the Advisory Action of June 9, 2005. The appealed claims are set forth in the attached Claims Appendix.

1. Real Party In Interest

This application is assigned to Scimed Life Systems, Inc., the real party in interest.

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2. Related Appeals and Interferences

A Notice of Appeal and an Appeal Brief were previously filed in this application in response to the final Office Action dated June 4, 2003. In view of the applicant's Appeal Brief, the Examiner re-opened prosecution introducing new grounds for a non-final rejection prior to a decision on the merits by the Board of Patent Appeals and Interferences. *10/21/04 Office Action*. In response, the applicant elected to reply to the Examiner's rejection and did not request reinstatement of the prior appeal. Thus, the previous appeal has been vacated and will not have any bearing on the Board's decision in this appeal. The undersigned representative of the applicants is not aware of any other appeal or interference which will directly affect, be directly affected by, or have a bearing on, the Board's decision in this appeal.

3. Status of Claims

Claims 1 - 32 were previously canceled. Claims 33 - 42 were rejected in the final Office Action and are the subject of the instant appeal.

4. Status of Amendments

A Response to Final Rejection dated May 31, 2005 was considered, but was not deemed to place the application in condition for allowance. *6/9/05 Advisory Action*.

5. Summary of Claimed Subject Matter

The invention is directed to an apparatus and method for performing a tissue resectioning procedure. The apparatus includes a resection head mounted at a distal end of an elongate flexible body. *Specification*, p. 4, lines 24 - 28. When in an operative position, the resection head is located within a body lumen with the elongate flexible body extending through the body lumen from a naturally occurring body orifice. *Id.* at p. 6, lines 9 - 11. An imager,

which remains outside the patient's body, generates image data of a selected region within the body including a predetermined portion of tissue marked for resection. *Id.* at p. 5, line 26 - p. 6, line 2. An image processing unit analyzes the image data to define a region of tissue to be resected and to locate a marker on the resection head. A control unit controls the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue. *Id.* at p. 6, lines 18 - 29.

6. Grounds of Rejection to be Reviewed on Appeal

- I. Whether the specification fails to provide proper antecedent basis for claimed subject matter under 37 C.F.R. 1.75(d)(1) and MPEP § 608.01(o).
- II. Whether claims 33 - 36 and 40 are unpatentable under 35 U.S.C. § 103(a) as obvious over McGuckin, Jr. (U.S. Patent No. 5,868,760) in view of Murphy-Chutorian (U.S. Patent No. 5,891,133).
- III. Whether claim 37 is unpatentable under 35 U.S.C. § 103(a) as obvious over McGuckin, Jr. in view of Murphy-Chutorian in further view of Osterholm (U.S. Patent No. 4,830,849).
- IV. Whether claims 38 - 39 are unpatentable under 35 U.S.C. § 103(a) as obvious over McGuckin, Jr. in view of Murphy-Chutorian in further view of Aida (U.S. Patent No. 5,485,839).
- V. Whether claims 41 - 42 are unpatentable under 35 U.S.C. § 103(a) as obvious over McGuckin, Jr. in view of Murphy-Chutorian in further view of Kreizman et al. (U.S. Patent No. 6,214,018).

7. Argument

- I. The Objection to the Specification for Failure to Provide Proper Antecedent Basis for Claimed Subject Matter Should be Reversed

In the final Office Action, the Examiner asserted that the specification fails to provide proper antecedent basis for claimed subject matter and must be corrected to include the term "naturally occurring body orifice."

Initially, it should be noted that an amendment to the specification was submitted in a Response Under Rule 116 dated May 31, 2005. The amendment, in relevant part, stated

The endoscope is inserted into a naturally-occurring body orifice to locate a lesion, for example, in a tubular organ under visual observation (usually while insufflating the organ).

5/31/05 Response (emphasis in original). In the Advisory Action, the Examiner stated that the response was considered, but gave no indication as to whether the amendment to the specification was entered. That is, the comments in the Advisory Action did not indicate that the Examiner entered the amendment and/or withdrew the objection to the specification. However, if the amendment was entered, Applicant respectfully submits that the objection to the specification should be withdrawn as the term “naturally occurring body orifice” is now defined therein.

Even if the amendment to the specification was not entered, Applicant respectfully submits that the application provides ample antecedent basis for the term “naturally occurring body orifice.” In response to the final Office Action filed September 4, 2003, the specification was amended to include subject matter from a patent incorporated by reference into the present application. Specifically, the specification was amended to state that the “endoscope is inserted into a body orifice to located a lesion, for example, in a tubular organ under visual observation (usually while insufflating the organ).” Applicant respectfully submits that those of skill in the art would understand that the description of a body orifice refers to naturally occurring orifices and that this description provides clear antecedent basis for the claim term “naturally occurring body orifice,” as recited in claim 33.

Therefore, Applicant respectfully submits that, whether the amendment to the specification under Rule 116 was entered or not, the terms used in the specification provide clear support for the term “naturally occurring body orifice” as recited in claim 33, and that this claim fully complies with 37 C.F.R. 1.75(d)(1) and MPEP § 608.01(o).

II. Whether claims 33 - 36 and 40 are unpatentable under 35 U.S.C. § 103(a) as obvious over McGuckin, Jr. (U.S. Patent No. 5,868,760) in view of Murphy-Chutorian (U.S. Patent No. 5,891,133)

In the final Office Action the Examiner asserted that McGuckin, Jr. discloses a tissue resectioning system including a resection head mounted at a distal end of an elongate flexible body, a diagnostic imager providing guidance of the resectioning head and a control unit, but fails to disclose the use of a marker on the resection head. *3/31/05 Office Action*, p. 2. The Examiner stated that a marker as claimed is shown on the resectioning device of Murphy-Chutorian and that the combination of McGuckin, Jr. and Murphy-Chutorian renders the claimed invention obvious to one of skill in the art. *Id.*

Claim 33 recites a tissue resectioning system, comprising “a resection head mounted at a distal end of an elongate flexible body, *the resection head including a marker thereon* wherein, when in an operative position, the resection head is located within a body lumen with the elongate flexible body extending through the body lumen from a naturally occurring body orifice” and “*an imager which remains outside the patient’s body, the imager generating image data of a selected region within the patient’s body including a predetermined portion of tissue marked for resection*” in combination with “an image processing unit analyzing the image data to define a region of tissue to be resectioned and to locate the marker” and “*a control unit controlling the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue.*”

In contrast, McGuckin, Jr. describes an apparatus for endoluminally resecting tissue which consists of a tubular member 16 connected to an operating capsule 12 at a distal end, and a operator control module 14 at a proximal end. *McGuckin, Jr.*, col. 11, lines 58-67. An endoscope 216, with a control segment 222 at a proximal end thereof, is passed through the tubular member 16 to an opening in the operating capsule 12. *Id.* at col. 12, lines 9-20. The control segment 222 of the endoscope 216 includes an eyepiece 224, an input light source 226 and fiberoptics extending from the eyepiece 224 to a distal tip of the endoscope 216 in the

operating capsule 12. *Id.* at col. 12, lines 15-20. The fiberoptics provide a physician with an interior view of a path through the colon to a site where the tissue to be resected is located. *Id.* at col. 12, lines 38-44.

Although McGuckin, Jr. states that the system is not limited to any particular type of diagnostic imaging guidance, no further description of guidance systems other than a vision system at the distal end of an endoscope is provided. *Id.* at col. 3, lines 59-65. That is, the device of McGuckin, Jr. is controlled based only on direct vision of the location to be operated on via the vision system at the distal tip extremity 218 of the endoscope 216. The vision system provides the physician with “a view ahead as...[the] endoscope 216 is advanced along the tortuous path defined by the colon.” *Id.* at col. 12, lines 39-43. Further, “the endoscope may have the viewing fiberoptics connected to a television camera...permitting the physician...to view the interior of the colon (as seen from tip extremity 218) on a high resolution television screen.” *Id.* at col. 12, lines 43-49. Even in this embodiment, the vision system still only presents the view of the interior of the colon. Furthermore, McGuckin, Jr. includes no showing or suggestion of any control of a resection head based on any imaging data besides manual control based on vision from the distal end of the endoscope. Thus, it is respectfully submitted that McGuckin, Jr. neither discloses nor suggests “an imager which remains outside the patient’s body,” as recited in claim 33.

As the Examiner has correctly recognized, McGuckin, Jr. does not disclose or suggest the use of a resection head with a marker thereon. Without disclosing the marker, it follows that McGuckin, Jr. also does not show or suggest “an image processing unit analyzing the image data...to locate the marker” or “a control unit controlling the resection head based on...the location of the marker to resect the region of tissue,” as recited in claim 33. The Examiner has attempted to cure the deficiencies of McGuckin, Jr. with the disclosure of Murphy-Chutorian. Murphy-Chutorian discloses a device for performing intra-coronary laser-assisted transmyocardial revascularization (ITMR). The ITMR device utilizes laser delivery means 162 to create channels 210 from the epicardial to the endocardial portions of the heart, allowing blood

to perfuse therethrough. *Murphy-Chutorian*, col. 12, lines 7-29.

Initially, it should be noted that the device described in *Murphy-Chutorian* does not perform resection of tissue. The laser delivery means 162 only creates channels in the myocardium, and, the reference includes no suggestion that the device could be used to resect tissue nor is there any suggestion that such resection would be of any benefit in such a device. Thus, a resection head at a distal end of an elongate flexible body is neither disclosed nor suggested by *Murphy-Chutorian*. Furthermore, the device of *Murphy-Chutorian* is not introduced into the body via a naturally occurring body orifice. As this device is for use within the vascular system, entry through a naturally occurring body orifice is not possible. Rather the device is inserted into the femoral artery after a surgeon has gained access to such “using a standard needle to probe and find the femoral artery.” *Murphy-Chutorian*, col. 10, lines 6-7. The device of *Murphy-Chutorian* also contains visualization means on the distal end of a catheter 140 that houses the laser delivery means 162. Thus, the visualization means is not an imager which remains outside of a patient’s body. Thus, it is respectfully submitted that *Murphy-Chutorian* neither discloses nor suggests either a device for resecting tissue which is inserted into the body via a naturally occurring body orifice or an imager which remains outside the body, as recited in claim 33 and clearly neither shows nor suggests “*a control unit controlling the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue,*” where the region of tissue is defined based on imaging data obtained from a device outside the body.

Accordingly, for at least the reasons described above, Applicant respectfully submits that neither McGuckin, Jr. nor *Murphy-Chutorian*, either alone or in combination, shows or suggests a tissue resection system comprising: “a resection head located within a body lumen with an elongate flexible body extending through the body lumen from a naturally occurring body orifice” in combination with “an imager which remains outside the patient’s body generating image data of a selected region within the patient’s body including a predetermined portion of tissue marked for resection and an image processing unit analyzing the image data to

define a region of tissue to be resected and to locate the marker” and “a control unit controlling the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue,” as recited in claim 33. Because claims 34-36 and 40 depend from, and, therefore include all of the limitations of claim 33, it is respectfully submitted that these claims are also allowable and that the Board should reverse the rejections thereof.

III. Whether claim 37 is Unpatentable Under 35 U.S.C. § 103(a) as Obvious over McGuckin, Jr. in View of Murphy-Chutorian in Further View of Osterholm (U.S. Patent No. 4,830,849)

Osterholm describes a system for circulating an oxygenated nutrient emulsion through a portion of the cerebrospinal pathway as a treatment for ischemic neurologic tissue. Applicant respectfully submits that Osterholm does not cure the above-described deficiencies of McGuckin, Jr. and Murphy-Chutorian. Thus, because claim 37 depends from, and, therefore includes all of the limitations of claim 33, it is respectfully submitted that this claim is also allowable and that the Board should reverse the rejection thereof.

IV. Whether claims 38 - 39 are unpatentable under 35 U.S.C. § 103(a) as obvious over McGuckin, Jr. in view of Murphy-Chutorian in further view of Aida et al. (U.S. Patent No. 5,485,839)

Aida purports to show a tissue therapy system including an alarm means to notify an operating physician of a deviation from a predetermined treatment plan. However, Aida et al. is directed to a non-surgical device -- an ultrasonic device for the treatment of calculi. Thus, it is respectfully submitted that Aida does not cure the above-described deficiencies of McGuckin, Jr. and Murphy-Chutorian. Because claims 38 and 39 depend from, and, therefore include all of the limitations of claim 33, it is respectfully submitted that these claims are also allowable and that the Board should reverse the rejection thereof.

- V. Whether claims 41 - 42 are unpatentable under 35 U.S.C. § 103(a) as obvious over McGuckin, Jr. in view of Murphy-Chutorian in further view of Kreizman et al. (U.S. Patent No. 6,214,018)

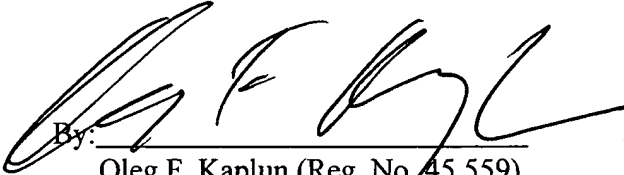
Kreizman et al. shows a rigid device requiring a body part holder to hold immobile a body part including tissue to be removed so that a point of reference may be defined relative to the immobilized body part. Applicant respectfully submits that such a system is wholly unsuitable for use with a flexible device inserted via a naturally occurring body orifice as claimed and that, therefore, Kreizman does not cure the above-described deficiencies of McGuckin, Jr. and Murphy-Chutorian. Because claims 41 and 42 depend from, and, therefore include all of the limitations of claim 33, it is respectfully submitted that these claims are also allowable and that the Board should reverse these rejections.

8. Conclusion

For the reasons set forth above, the appellee respectfully requests that the Board reverse the objection to the specification under 37 C.F.R. 1.75(d)(1) and MPEP § 608.01(o) and the final rejections of the claims under 35 U.S.C. § 103(a) and indicate that claims 33 - 42 are allowable.

Respectfully submitted,

Date: October 7, 2005


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CLAIMS APPENDIX

33. A tissue resectioning system, comprising:

a resection head mounted at a distal end of an elongate flexible body, the resection head including a marker thereon wherein, when in an operative position, the resection head is located within a body lumen with the elongate flexible body extending through the body lumen to a naturally occurring body orifice;

an imager which remains outside the patient's body, the imager generating image data of a selected region within the patient's body including a predetermined portion of tissue marked for resection;

an image processing unit analyzing the image data to define a region of tissue to be resected and to locate the marker; and

a control unit controlling the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue.

34. The system according to claim 33 wherein the imager includes a fluoroscope and an x-ray imaging sensor.

35. The system according to claim 33 wherein the marker is radiopaque.

36. The system according to claim 33 wherein the defined region of tissue and the location of the marker are displayed on a video display coupled with the control unit.

37. The system according to claim 33 wherein the control unit disables the resection head if the marker indicates that the resection head is oriented outside the defined region of tissue.

38. The system according to claim 33 further comprising an alarm device wherein the control unit transmits an alarm signal to the alarm device when the marker indicates that the resection

head is oriented outside the defined region of tissue.

39. The system according to claim 38 wherein the alarm device generates a visual alarm.

40. The system according to claim 33 wherein the imager is a magnetic resonance imager.

41. The system according to claim 33 wherein the image processing unit determines the defined region of tissue by an absolute measure of tissue.

42. The system according to claim 33 wherein the image processing unit determines the defined region of tissue by a percentage of a physical dimension of the lesion.

EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.